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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,653

01/22/2004

Leonard Schlessinger

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EXAMINER

SIMS, JASON M

ART UNIT

PAPER NUMBER

1631

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/763,653	<b>Applicant(s)</b> SCHLESSINGER ET AL.	
	<b>Examiner</b> JASON M. SIMS	<b>Art Unit</b> 1631	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 10 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-10,31-40,52 and 61-75.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

/Michael Borin/  
 Primary Examiner, Art Unit 1631

Continuation of 3. NOTE: The proposed amendments introduce new claims, such as claims 76-81, and new limitations not previously considered and therefore could cause a new search and consideration. With respect to amended claims applicant's arguments have been considered, but are not found persuasive as they address not entered amendments.

Continuation of 11. does NOT place the application in condition for allowance because:

With regards to applicant's arguments with respect to claim 3, applicant repeats arguments previously submitted in their response filed 6/10/2008 wherein the office's position with regards to the arguments have been restated herein:

Applicant argues that Van Holde (1996) does not teach limitations for "Fasting Plasma Glucose," which relate to a more specific characterization than simply "glucose level in the blood."

Applicant's arguments are not found persuasive as Van Holde (1996) at page 826, under Responses to metabolic stress, second paragraph describe the relationship between glucose levels and insulin after a meal, i.e. "Fasting Plasma Glucose," which also describes effects on the production of glucose, i.e. basal hepatic production. Furthermore, Van Holde (1996), page 828-829 also describes the relationship between glucose levels and insulin under other conditions such as diabetes, wherein insulin may be defective and as a result glucose is actually present in excessive amounts. In addition, applicant has not defined or limited that term "fasting plasma glucose" in the instant specification and therefore, glucose levels in the blood after a meal, read on the definition of a "fasting plasma glucose" value.

Applicant further argues that inherency was improperly relied upon in support of the rejection.

Applicant's arguments are not found persuasive they do not point out what exact limitation inherency was relied upon in support of the instant rejection. Therefore, it is unclear as to what exactly applicant's are arguing with respect to stating inherency was improperly relied upon.

Applicant further argues that representing relationships generically and mathematically provides no reasonable expectation of success for the modification proposed with respect to this rejection.

Applicant's arguments are not found persuasive because applicants argue that the mathematical arrangement which describes a relationship between events is unobvious and unpredictable from that of a verbal description about the same relationship between events. For example, Van Holde (1996) describes the relationship between insulin and glucose levels as such that if you increase insulin levels then blood glucose levels decrease and vice versa under normal circumstance. Therefore, the verbal description of the relationship is teaching that there is an inverse relationship between the two levels, which in mathematics is represented through an inverse function as described. Furthermore, Van Holde (1996) describes how insulin functionality may be effected by events such as mutations, which would cause insulin to not work with 100% efficiency. Therefore, the verbal description is teaching that the insulin value may be altered by a factor between 0-100% in the event such as a mutation, wherein mathematics this effect is often represented through the use of a weighting parameter. Therefore there is nothing found unpredictable about the mathematical relationship claimed and the verbal description provided by Van Holde (1996).

Applicant further argues that the office action does not point out any quantitative characterization of efficiency or even any specific discussion of efficiency in the cited reference.

Applicant's arguments are not found persuasive because in the office action it was stated that Van Holde (1996) at page 829 teaches that there may be several reasons for the cause of diabetes, such as a mutation in the insulin structure or mutations in the insulin receptors or molecules involved in the conversion of molecules into insulin all of which effect the efficiency of role of insulin. Therefore, to represent the efficiency of insulin under said conditions, it would have been obvious to one of ordinary skill in the art to represent the efficiency of insulin as somewhere between 0-1 depending on the condition and cause and the results would have been unobvious and predictable..